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ARIOSA DIAGNOSTICS, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

VERINATA HEALTH, INC., Plaintiff and Counterclaim-Defendant, vs. ARIOSA DIAGNOSTICS, INC., Defendant and Counterclaim-Plaintiff.	Lead Case No. 3:12-cv-05501-SI Case No. 3:14-cv-01921-SI Case No. 3:15-cv-02216-SI **ARIOSA DIAGNOSTICS, INC.'S, NOTICE OF MOTION AND MOTION FOR JUDGMENT AS A MATTER OF LAW UNDER RULE 50(b) AND MOTION FOR NEW TRIAL UNDER RULE 59 ON ISSUES FOR WHICH ARIOSA BORE THE BURDEN OF PROOF; MEMORANDUM IN SUPPORT** Judge: Hon. Susan Illston Date: April 6, 2018 Time: 9:00 am Ctrm.: 1, 17th Floor
ILLUMINA, INC., Plaintiff and Counterclaim-Defendant vs. ARIOSA DIAGNOSTICS, INC., Defendant and Counterclaim-Plaintiff.	

ILLUMINA, INC.,

Plaintiff and Counterclaim-Defendant

vs.

ARIOSA DIAGNOSTICS, INC.,

Defendant and Counterclaim-Plaintiff.

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NOTICE OF MOTION AND MOTION

PLEASE TAKE NOTICE that on April 6, 2018 at 9:00 am, or as soon thereafter as the matter may be heard by the Honorable Judge Susan Illston in Courtroom 1, 17th floor of the United States District Court for the Northern District of California, 450 Golden Gate Ave, San Francisco, CA 94102, Defendant and Counterclaim Plaintiff Ariosa Diagnostics, Inc. ("Ariosa") hereby moves for renewed judgment as a matter of law ("JMOL") on its license defense, its affirmative counterclaims, and its invalidity defenses pursuant to Fed. R. Civ. P. 50(b) and for a new trial pursuant to Fed. R. Civ. P. 59. The jury verdict against Ariosa on its license defense, its affirmative counterclaims, as well as its invalidity defenses, is not supported by substantial evidence, and alternatively, and at a minimum, is against the great weight of the evidence. Finally, Plaintiffs' presentation of misleading argument and multiple violations of Court orders also warrant a new trial on these issues.

This Motion is based on this notice of motion and supporting memorandum of points and authorities, the testimony and evidence admitted at trial, all pleadings, exhibits, and records in this action, and such other evidence and argument as may be submitted to the Court in connection with this Motion or that the Court may take notice or otherwise consider.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Ariosa renews its motion for judgment as a matter of law on issues for which Ariosa bore the burden of proof at trial: its license defense, its affirmative counterclaims, and its invalidity defenses; and in the alternative moves for a new trial on those issues. Fed. R. Civ. P. 50(b), 59. The jury verdict is not based on substantial evidence, and at minimum is against the great weight of the evidence.

II. ARGUMENT

A. A Reasonable Jury Could Only Find In Ariosa's Favor On Its Affirmative Defense Of Express License

The grant of a license to practice a patented technology provides a complete defense to a claim for patent infringement. *See Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1364 (Fed. Cir.

2003). The language of the 2012 Sale and Supply Agreement between Ariosa and Illumina (the "SSA") and Illumina's infringement theory establish that Illumina granted Ariosa an express license to the '794 patent for its Harmony Version 1 test ("V1" or "Harmony V1") and that Illumina breached that license by suing Ariosa for infringement of that patent for V1.

1. The SSA Granted Ariosa A License To The '794 Patent

Under California law, where extrinsic evidence supporting an interpretation of a contract is not conflicting, the court should interpret the contract as a matter of law. *Wolf v. Walt Disney Pictures & Television*, 162 Cal. App. 4th 1107, 1126 (2008), *as modified on denial of reh'g* (June 4, 2008) ("When there is no material conflict in the extrinsic evidence, the trial court interprets the contract as a matter of law."). Further, "[t]he parties' undisclosed intent or understanding is irrelevant to contract interpretation." *Founding Members of the Newport Beach Country Club v. Newport Beach Country Club, Inc.*, 109 Cal. App. 4th 944, 956 (2003). As a result, the testimony of both sides' witnesses concerning their personal understanding of the meaning of the SSA is irrelevant under California law to the interpretation of the agreement.[1] *Id.*

In this case, there is no conflicting extrinsic evidence as to the meaning of the terms "Core IP Rights in Goods" and "Secondary IP Rights in Goods" under the SSA, and the Court should interpret the SSA as a matter of law. The SSA defines "Core IP Rights in Goods" as "those Illumina Intellectual Property Rights that pertain to the Goods (and use thereof in accordance with their Documentation) other than Secondary Illumina IP Rights in Goods[.]" Ex. 615[2] (SSA) at § 1. The SSA defines "Goods" to include Illumina's sequencers and sequencing reagents. *Id.* at Ex. B. The SSA grants a license to Ariosa under "Core IP Rights in Goods to use and import … the Goods only in the Customer Field of Use," defined in relevant part as "commercial services for the cell-free detection of fetal chromosomal abnormalities … using DNA sequencing…." *Id.* at

[1] However, testimony from Ariosa's witnesses as to their understanding of the SSA was relevant to the separate issue of willful infringement. The reasonable, good faith belief of Ariosa's witnesses that Ariosa was licensed to the '794 patent for Harmony V1 refuted Plaintiffs' claim that Ariosa's alleged infringement of the '794 patent for Harmony V1 was willful. *See, e.g.*, Trial Tr. 778:20-779:1; 809:24-819:25; 847:20-848:12 (Dr. Stuelpnagel). The jury agreed that Ariosa did not willfully infringe the '794 patent.

[2] "Ex." refers to exhibits to the Declaration of Sandra L. Haberny, filed concurrently with and in support of Ariosa's Motions.

§§ 3(a), 1. The SSA defines "Secondary IP Rights in Goods" as "the secondary Illumina Intellectual Property Rights that pertain to the Goods (and use thereof) only with regard to particular field(s) or application(s), and are not common to the Goods in all applications and fields." *Id.* Thus, there are only two questions of relevance to determine whether the '794 patent is licensed under the SSA: whether the '794 patent is application-specific such that it is "Secondary IP," and whether the '794 patent "pertains to" Ariosa's use of the Illumina Goods sold under the SSA.

First, it is clear from the evidence presented at trial that the '794 patent is not "Secondary IP" under the SSA, because it is not particular to any one application. *See* Ex. A (Trial Tr.) 1162:6-8 (Mr. Eidel) ("Q. Does Illumina consider the '794 patent to be application-specific? Yes or no? A. No."); *id.*, 1039:15-20 (Dr. Cooper) ("The '794 can be used in a number of applications, yes."); Ex. 513 ('794 Patent) at col. 11:50-54 ("In one embodiment the use of adapter sequences allow the creation of more "universal" surfaces; that is, one standard array, comprising a finite set of capture probes can be made and used *in any application*.") (emphasis added). Thus, under the plain language of the SSA, the '794 patent is not excluded from the definition of "Core IP."

Since it is not excluded as Secondary IP, the remaining question is whether the '794 patent falls within the definition of "Core IP," *i.e.*, whether the '794 Patent "***pertain[s] to***" Ariosa's use of Illumina's sequencers (the "Goods") in Harmony V1. Ex. 615 at § 1 (emphasis added). Under California law, "[t]he words of a contract are to be understood in their ordinary and popular sense." Cal. Civ. Code § 1644. "In determining the plain meaning of language in a contract, a court may look to a 'general' dictionary definition to aid in its analysis." *Flintkote Co. v. Gen. Accident Assurance Co.*, 410 F. Supp. 2d 875, 887 (N.D. Cal. 2006). The word "pertain" is commonly defined as "be appropriate, related, or applicable to." *Pertain*, Oxford English Dictionary (4th ed. 2006); *see also Pertain*, American Heritage College Dictionary (4th ed. 2007) (defining "pertain" as to "have reference; relate").

When addressing the interpretation of a similar term—"relate to"—in the very same agreement, this Court observed that, under Supreme Court precedent, "the phrase 'relate to' has a 'broad common-sense meaning,' such that 'relate to,' in the normal sense of the phrase, means to

have 'a connection with or reference to.'" D.I. 97 at 6 n.3 (citing *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 47 (1987) and *Shaw v. Delta Air Lines*, 463 U.S. 85, 97 (1983)). In other cases, the Supreme Court has held that the "ordinary meaning" of the words "relating to" is a broad one—"to stand in some relation; to have bearing or concern; to pertain; refer; to bring into association with or connection with." *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383 (1992); *see also Barnett Bank of Marion Cty., N.A. v. Nelson*, 517 U.S. 25, 38 (1996) ("In ordinary English, a statute that says that banks may act as insurance agents, and that the Comptroller of the Currency may regulate their insurance-related activities, 'relates' to the insurance business. The word 'relates' is highly general."); *accord Harkonen v. Sebelius*, No. C 13-0071 PJH, 2013 WL 5734918, at *7 (N.D. Cal. Oct. 22, 2013) (holding that "the phrases 'in connection with,' 'in relation to,' or 'related to' are generally interpreted expansively"). California state courts concur. *See, e.g., Bay Cities Paving & Grading, Inc. v. Lawyers' Mut. Ins. Co.*, 5 Cal. 4th 854, 868 (1993) ("'Related' is a commonly used word with a broad meaning that encompasses a myriad of relationships. For example, a leading legal dictionary defines 'related' to mean 'standing in relation; connected; allied; akin.'") (citing Black's Law Dictionary 1288 (6th ed. 1990)); *In re Jorge G.*, 117 Cal. App. 4th 931, 941 (2004) (same).

The '794 patent plainly "relates to"/"has a connection with"/is "applicable to" Ariosa's use of Illumina's sequencers (the Goods) that Ariosa purchased from Illumina to perform its Harmony test, and hence the patent "pertains to" those Goods under the ordinary meaning of that term. This is confirmed by Illumina's own infringement theory against Harmony V1, which expressly relied on Ariosa's use of those sequencers to satisfy the critical "detecting" step of the '794 patent. Illumina's expert, Dr. Cooper, agreed that "all of the steps of the claim ultimately are leading to this detecting step," and that "the point of the whole assay is that these target sequences can be detected." Trial Tr. 1036:4-10. According to Dr. Cooper, in Harmony V1, Ariosa fulfilled this ultimate goal of the method of the '794 patent precisely through the use of Illumina's sequencers:

Q. So Ariosa bought sequencers from Illumina; correct?

A. Yes. …

> Q. And you're saying that Ariosa infringes the '794 patent, in part, by attaching their amplicons to the flow cell that Illumina sold Ariosa under their Sale and Supply Agreement; correct?
>
> A. Well, I would say that the Illumina flow cell is serving as the second solid support that is discussed in F and G of the '794 patent Claim 1.
>
> ***Q. And then the detecting step -- you claim that Ariosa infringes the '794 patent when, as the goal of the whole assay, Ariosa uses an Illumina sequencer that Ariosa bought from Illumina to detect the amplicons and do the sequencing as claimed; correct?***
>
> ***A. Yes.*** The Illumina sequencer provides the information to detect the—the target sequences via the amplicon immobilization to the flow cell…
>
> Q. … just so that we're clear, you're relying on Ariosa's use of the Illumina flow cell, and the use of the Illumina sequencer to support your infringement opinion under the '794 patent for Version 1; correct?
>
> A. Yes, it fulfills the portions of the F and G, Yes.

Trial Tr. 1037:5-1038:15 (emphasis added). There simply can be no doubt, in light of Illumina's own infringement theory, that the '794 patent pertains to the Goods—the sequencers—that Illumina sold Ariosa under the SSA. The '794 patent thus has "a connection with" Illumina's sequencing equipment and clearly fits within the definition of "Core IP Rights in Goods."

Throughout trial, Illumina attempted to rewrite the language of the SSA to argue that "Core IP Rights" only includes patents that are ***required*** for use of the Illumina sequencers. *See, e.g.*, Trial Tr. 143:10-12 (opening statement) ("If you have to do it—*it's inherent in the use of the sequencer*—that's what Core IP Rights are.") (emphasis added). This argument should have absolutely no bearing on the outcome of this case because, as discussed above, a party's "undisclosed intent or understanding is irrelevant to contract interpretation." *Founding Members*, 109 Cal. App. 4th at 956.

Moreover, Illumina's self-serving interpretation of "Core IP" to include only patents that are ***inherent*** in the use of Illumina's sequencers would improperly render the "Core IP" provision meaningless—because Ariosa automatically received rights to all patents that are inherently practiced in the use of Illumina's sequencers under the doctrine of patent exhaustion. "The longstanding doctrine of patent exhaustion provides that the initial authorized sale of a patented item terminates all patent rights to that item." *Quanta Comput., Inc. v. LG Elecs., Inc.*, 553 U.S.

617, 625 (2008). Patent exhaustion is triggered where the "only reasonable and intended use" of the product sold "was to practice the patent" in question. As a result, Illumina's sale of sequencers to Ariosa under the SSA automatically exhausted Illumina's right to enforce against Ariosa any patents that were inherently practiced in the use of those sequencers. *See id.* at 631.

Thus, Plaintiffs' contention that the express license to Core IP Rights provides nothing more than rights to those same exhausted patents would render Illumina's grant of an express license to Ariosa nugatory. Plaintiffs' interpretation violates one of the most fundamental canons of contract interpretation: "a contract should be interpreted so as to give meaning to each of its provisions." *See Brinderson-Newberg Joint Venture v. Pac. Erectors*, 971 F.2d 272, 278-79 (9th Cir. 1992) (applying California law). A court therefore "must interpret contractual language in a manner that gives force and effect to every provision, and not in a way that renders some clauses nugatory, inoperative or meaningless." *Ward v. Goossen*, 71 F. Supp. 3d 1010, 1014 (N.D. Cal. 2014) (applying California law). As a result, Plaintiffs' interpretation of the SSA fails as a matter of law.

Given that the evidence at trial established that the '794 patent was part of the Core IP rights licensed to Ariosa under the SSA, as a matter of law that license to practice the '794 patent is a complete defense to Illumina's infringement claim with respect to Harmony V1 and judgment should be entered in favor of Ariosa on that claim.

2. Illumina Breached The SSA By Suing Ariosa On The '794 Patent

The same analysis of the SSA also requires a finding that Ariosa is entitled to judgment as a matter of law on its affirmative claim for breach of contract against Illumina. Given that the SSA affirmatively licensed the '794 patent to Ariosa as part of the Core IP, that license barred Illumina from suing Ariosa for infringement of that patent. "A nonexclusive license is a covenant not to sue[,]" and "the initiation of a lawsuit for infringement despite the existence of a valid license agreement may serve as the basis for a breach of contract claim." D.I. 517 at 14 (citing *Morrow v. Microsoft Corp.*, 499 F.3d 1332, 1346 (Fed. Cir. 2007)). In breach of that express license, Illumina sued Ariosa for infringement of the '794 patent for Harmony Version 1, and thus JMOL on Ariosa's claim that Illumina breached the SSA is warranted here. Because the jury erroneously

found against Ariosa on the issue of breach, a finding that is not supported by substantial evidence, the jury did not reach the issues of damages. As a result, the Court should grant Ariosa a new trial on that issue.[3]

B. The Court Should Grant JMOL, Or Alternatively A New Trial, On Invalidity

1. The Court Should Grant JMOL Or A New Trial On Anticipation Of The '794 Patent By The Straus Patent Application

Ariosa is entitled to judgment as a matter of law that the '794 patent is invalid as anticipated by the Straus reference. Ex. 1044. Alternatively, Ariosa is entitled to a new trial on this issue. Ariosa's expert, Dr. Cantor, provided unrebutted testimony that the specification of Straus, including Figure 5, disclosed all of the elements of the asserted claims of '794 patent. Trial Tr. 1465:16-18 (describing Straus as "exactly the same" as the '794 patent); *id.*, 1467:9-1476:7 (mapping all elements of '794 patent claims to Straus reference); Ex. 1044. Plaintiffs' responses to Dr. Cantor's testimony fail as a matter of law.

First, Dr. Cooper made the legally spurious assertion that anticipation required the disclosure of "all elements of the claim have to be *in one disclosure or figure*" in the disclosure of the Straus reference. Trial Tr. 1599:4-9. In particular, Dr. Cooper contended that Figure 5 itself in isolation did not disclose all of the '794 patent claim elements, Trial Tr. 1500:23-1504:1; *id.*, 1599:1-9, and that the additional disclosure in the Straus specification should be disregarded because three elements—"at least 100 different target sequences," "more than 100 different single stranded probes," and "identical universal priming sites"—were mentioned in the text of that disclosure but not expressly linked to Figure 5.[4]

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[3] Ariosa presented evidence at trial showing that Ariosa was substantially harmed by this breach, exceeding the amount of $14.4 million paid by Ariosa to Illumina under the SSA. *See, e.g.*, Trial Tr. 1545:4-12 (Dr. Sullivan) ("Q. So taking together all of those different methods you took to look at the issue of harm, what is your ultimate take-away regarding Ariosa's counterclaim damages? A. In my view the harm to Ariosa was substantial. And I have calculated that a reasonable and conservative estimate is $88.5 million. Q. How confident are you that the harm to Ariosa exceeds the $14 million we heard Ms. Yee talk about earlier? A. Extremely confident."); *id*, 1523:14-15 (Ms. Yee) ("Q. So how much did Ariosa pay Illumina under that agreement? A. So from 2012 to 2014, we paid about 14.4 million.").

[4] *See* Ex. 1044 at ¶ 39 ("In preferred embodiments, the probes of (a) include … more than two hundred and fifty[] different amplifiable probes"); *id.* at ¶ 138 ("For example, a family of ID sequences might consist of 100 ID sequences…"); *id.* at ¶ 176 (disclosing "using a very small

Dr. Cooper's improper testimony was contrary to settled case law on anticipation, as well as the Court's jury instruction on anticipation. "[A] claim is anticipated if each and every limitation is found either expressly or inherently *in a single prior art reference*." *Celeritas Techs., Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998) (emphasis added). Anticipation does not further require that all claim elements otherwise disclosed in a single prior art reference must also be disclosed in, or explicitly linked to, a single figure or passage of that prior art reference. Indeed, "a reference can anticipate a claim even if it does not expressly spell out all the limitations arranged or combined as in the claim, if a person of skill in the art, reading the reference, would at once envisage the claimed arrangement or combination." *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015) (quotations omitted).

Consistent with this settled law, the Court instructed the jury that for a claim to be anticipated, all of its requirements "must have been described in a single previous publication or patent that predates the claimed invention," Trial Tr. 1863:1-5. The legally erroneous standard for anticipation Dr. Cooper applied—which further required all of the claim requirements to be described in a *single figure or disclosure* of a prior art publication or patent—was thus also contrary to the Court's jury instruction on anticipation. Plaintiffs' counsel compounded Dr. Cooper's misstatement of the law on anticipation in his closing argument, improperly framing the issue as whether "Figure 5" of Straus discloses every step of the '794 patent claims. *Id.*, 1907:5-12 ("Well, let's see if Figure 5 does that."). But the issue the jury should have decided was whether the *Straus* prior art reference anticipates the claims of the '794 patent—not whether Figure 5 of Straus, standing alone, does so. *Kennametal, Inc.*, 780 F.3d at 1381.

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number of amplification sequences to direct the amplification of a large number of distinct ID probes," wherein that small number can be "one or more primer binding sites … common to most or all of the probes…"); Trial Tr. 1597:24-1598:9 (Dr. Cooper discussing claim requirement for "at least 100" only in the context of Figure 5); *id.*, 1598:10-1600:1 (Dr. Cooper discussing claim requirement for "more than 100 different single-stranded probes" only in the context of Figure 5); *id.*, 1600:2-1602:18 (Dr. Cooper discussing the "identical universal priming site" limitation but failing to rebut or address Dr. Cantor's opinions regarding the disclosure at Straus, Ex. 1044, at ¶ 176); *id.*, 1470:15-1471:15 (Dr. Cantor explaining disclosure of '794 patent "identical universal priming site" element in Straus at ¶ 176); *id.*, 1503:21-1404:1 (same).

Dr. Cooper's legally erroneous testimony does not provide substantial evidence to support the jury's verdict of no anticipation. Any reasonable review of Straus confirms that it anticipates the '794 patent. With respect to the elements Plaintiffs argue are not drawn out in Figure 5, Straus expressly discloses their use with his invention in the specification. Straus states that the "sequences" being analyzed in his method may "consist of 100 ID sequences." Ex. 1044 at ¶ 138; Trial Tr. 1468:8-20. Plaintiffs rebut this with the argument that the example illustrated in Figure 5 only depicts 48 different targets, but this is a straw man. Not only is the number of samples depicted purely illustrative in the figure, there is no suggestion in paragraph 138 or anywhere else in Straus that the disclosure of using "at least 100" different target sequences did not apply to Figure 5 or the entirety of the disclosure in Straus. Ex. 1044 at ¶ 138, Fig. 5; Trial Tr. 1468:8-20. Any suggestion to the contrary lacks credibility and cannot sustain a reasonable jury finding. *Arthrocare Corp. v. Smith & Nephew, Inc.*, 406 F.3d 1365, 1374 (Fed. Cir. 2005) (reversing district court's denial of JMOL of invalidity; patentee's expert's interpretation of figure in prior art reference did not constitute substantial evidence, where prior art "article speaks for itself" and "clearly" disclose[d]" disputed element).

The same legal flaws infect Plaintiffs' argument that Straus Figure 5, viewed in isolation, does not disclose "more than 100 different single-stranded probes" that each "has identical universal priming sites" ('794 patent, step 1(b)). Straus expressly states that his invention may include "more than two hundred and fifty[] different amplifiable probes." Ex. 1044 at ¶ 39; Trial Tr. 1470:5-14. Straus also expressly states that his invention "avoids the usual amplification artifacts that arise during multiplex amplification by using a very small number of amplification sequences to direct the amplification of a large number of distinct ID probes," providing as an example that the probes contain "one or more primer binding sites" that are "common to most or all of the probes." Ex. 1044 at ¶ 176. As Dr. Cantor explained, Straus's disclosure of "more than two hundred and fifty different amplifiable probes" and "one" binding site "common to . . . all of the probes" plainly discloses the disputed requirements of step 1(b)—namely, "more than 100 different single-stranded probes" that each "has identical universal priming sites." Trial Tr. 1470:15-1471:15; *id.*, 1503:20-1504:1; *id.*, 1504:15-21.

Dr. Cooper's only response was to point to *other* passages in Straus that he interpreted as implying the use of more than one universal priming site. Trial Tr. 1602:4-14. But these passages cannot negate Straus's clear teaching in the passages discussed above. Courts routinely reject attempts to distinguish prior art because it teaches functions in addition to the claimed functions, as Dr. Cooper tried to do. *See, e.g.*, *Orion IP, LLC v. Hyundai Motor Am.*, 605 F.3d 967, 977 (Fed. Cir. 2010) (finding anticipation as a matter of law and rejecting plaintiffs' attempt to distinguish prior art because it taught certain functions in addition to the claimed function); *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1319-20 (Fed. Cir. 2009) (reversing jury verdict and finding method patent anticipated where plaintiff tried to distinguish the prior art based on disclosed functions "in addition" to those claimed by the patent).

Indeed, Dr. Cooper admitted that Straus discloses using identical universal priming sites based on the very same universal priming site design in the Harmony V1 test that Plaintiffs argue infringes the '794 patent. Dr. Cooper admitted that in the method of the '794 patent claims, "it doesn't matter if not every probe in the assay has the same priming site, as long as 100 have the same first priming site." Trial Tr. 1650:18-23; *id.*, 1649:25-1650:17. Dr. Cooper also agreed that "the claims of the '794 patent speak of a first universal priming site," *id.*, 1650:24-1651:1, and that in universal PCR amplification, as carried out in the accused DANSR assay and claimed in the '794 patent, "a first site, and a second priming site which is different from the first," form a "pair of priming sites." *Id.*, 1651:2-1652:1 (further contending that this feature of DANSR infringes claim 1 of the '794 patent). Dr. Cooper finally admitted that "Straus discloses that the amplification step is carried out using … for example 'a single pair of amplification sequences to yield amplification products.'" *Id.*, 1654:7-17; Ex. 1044 at ¶ 0024. Indeed, Straus characterized this "single pair of amplification sequences" as included in the application's "preferred embodiments." Ex. at ¶ 0024. Dr. Cooper nevertheless resorted, again, to the same sham argument that this does not disclose the "identical universal priming site" as claimed in the '794 patent because the disclosure purportedly is not "linked to … Figure 5." Trial Tr. 1654:7-17.

In sum, Plaintiffs' only response to Ariosa's anticipation defense was to advance a legally erroneous standard for anticipation. When that erroneous theory is disregarded—as it should have

been by the jury—the evidence permits only one reasonable conclusion: the '794 patent is invalid for anticipation by Straus.

Alternatively, both the weight of the evidence and substantial prejudice to Ariosa warrant the grant of a new trial on the issue of anticipation by Straus. For the reasons set forth above, the jury's verdict of no anticipation is against the clear weight of the evidence proving anticipation. Moreover, Plaintiffs' counsel, in direct violation of this Court's order barring Plaintiffs from raising IPR proceedings at trial, substantially prejudiced Ariosa by both raising and mischaracterizing the excluded IPR proceedings to argue that the USPTO had substantively considered and rejected Straus as an anticipatory reference (which is untrue). *See* D.I. 547 at 6-7; Trial Tr. 738:20-739:13 (counsel improperly questioning witness about IPR proceedings); *id*., 1323:23-1325:4 (same); *id*., 1496:4-1498:21 (improper questioning witness about IPR, suggesting Straus had been substantively reviewed three times, and attempting to introduce IPR decisions as exhibits); *id*., 1511:3-13 (improper questioning witness about IPR proceedings); *id*., 1883:18-1884:2 (counsel confusingly raising IPR proceedings to improperly imply results during closing arguments); *id*., 1928:13-20 (counsel improperly referencing IPR proceedings during closing arguments); *id*., 1977:8-11 (same); *id*., 1978:5-6 (same). Plaintiffs' counsel's improper conduct unfairly influenced the verdict, at a minimum, by confusing the jury and convincing it that the USPTO had substantively rejected Ariosa's anticipation case (which, again, is both untrue and a violation of this Court's order). *See e.g., Wharf v. Burlington N. R.R. Co.*, 60 F.3d 631, 637-38 (9th Cir. 1995) (instructing that a party may be entitled to a new trial on the grounds of "fraud … misrepresentation, or other misconduct of an adverse party," and granting new trial based on improper attorney conduct that unfairly influenced the jury where counsel was permitted to read to jury an untruthful stipulated fact and argue false positions); *Molski v. M.J. Cable, Inc.*, 481 F.3d 724, 729 (9th Cir. 2007) ("Historically recognized grounds [for granting new trial] include, but are not limited to, claims that the verdict is against the weight of the evidence, that the damages are excessive, or that, for other reasons, the trial was not fair to the party moving."). Given Plaintiffs' blatant and repeated breach of this Court's order, and their reliance on a legally erroneous theory

of validity, the Court should, at a minimum, award a new trial on Ariosa's invalidity defense with respect to the '794 patent.

2. The '430 Patent Is Invalid For Lack Of Enablement

A patent must "enable any person skilled in the art ... to make and use" the claimed invention. 35 U.S.C. § 112(a). "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *ALZA Corp. v. Andrx Pharms.*, LLC, 603 F.3d 935, 940 (Fed. Cir. 2010); *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). "Enablement is a question of law based on underlying factual findings." *MagSil Corp. v. Hitachi Glob. Storage Techs., Inc.*, 687 F.3d 1377, 1380 (Fed. Cir. 2012).

The trial record compels the conclusion that the '430 patent is invalid under 35 U.S.C. § 112 for lack of enablement, and that no reasonable jury could conclude otherwise. First, it is undisputed that the '430 patent does not disclose an algorithm for "determining the presence or absence of a fetal aneuploidy" (step 1(f)) using a targeted (nonrandom) sequencing approach as claimed in the patent. Ex. 514 at col. 63:62-67; Trial Tr. 345:12-19 (Dr. Rava) ("Q. And so in terms of disclosing an algorithm that actually sets forth a determination using the nonrandom approach of the '430 patent, there is no specific articulation of such an algorithm in the text of the patent; fair statement? A. . . . Yes, there was no specific."); *id.*, 346:15-25 (Dr. Rava). Second, the patent also fails to address in any way the necessary elimination of variability and "noise" caused by the high proportion of maternal cell-free DNA ("cfDNA") in a sample, which quantitatively overwhelms the fetal cfDNA. Trial Tr. 1479:5-1481:12; *id.*, 1344:8-10; *id.*, 1345:16-1346:1. Finally, Dr. Rava, the only named inventor who testified at trial, admitted that the patent does not provide an example that would demonstrate that the claimed pooling and indexing would work for their intended purpose. *Id.*, 369:3-6.

The patentee's failure to reduce an invention to practice is strong evidence that the specification lacks enablement. *See Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1319 (Fed. Cir. 2007) (affirming grant of summary judgment of invalidity for lack of enablement). Here, the undisputed evidence established that Verinata never actually reduced the alleged invention of the

'430 patent to practice or used it in any of its own tests. Trial Tr. 262:15-23 (Dr. Bird); *id*., 349:1-5 (Dr. Rava); *id*., 351:7-9 (Dr. Rava); *id*., 1481:13-17 (Dr. Cantor). With respect to claim step (f) specifically, Dr. Rava further admitted that he "do[es]n't recall if [his] work on potentially using the method of the '430 patent ever got to the point of a fully formed algorithm." *Id*., 349:1-5.

Plaintiffs' only response at trial to the '430 patent's failure to disclose an algorithm that would enable step 1(f) was to point to a single sentence in the specification incorporating several prior art references. *Id*., 344:18-345:11 (Dr. Rava). But it is undisputed that these references do not relate to targeted sequencing; instead, they are directed to *random shotgun sequencing* approaches. *Id.*, 349:6-22 (Dr. Rava); *see* Ex. 514 at col.13:49-50 ("Methods for determining fetal aneuploidy using *random sequencing* techniques are described…") (emphasis added); Ex. 507A (discussing shotgun sequencing).

Even Dr. Rava acknowledged that the algorithm disclosed in these random shotgun sequencing references—involving the use of a "Z score"—could not be used as-is in the nonrandom approach claimed in the '430 patent. Trial Tr. 345:7-11. While he speculated that the algorithm would only have to be "optimized" for the nonrandom approach, he admitted that "you don't necessarily know that the same types of ratios that worked, or the same types of comparisons that worked would be identical." *Id.* It is also undisputed that Ariosa, for its part, tried, but rejected a Z-score approach. *Id*., 1358:5-6; *id.*, 1480:19-1481:5 (Dr. Cantor explaining that the approach used in the random shotgun sequencing methods of the incorporated references does not work in the claimed nonrandom method).

In fact, the trial record established that developing an algorithm for a nonrandom approached as claimed—which the '430 patent indisputably fails to disclose, *id.*, 345:12-19—would have required undue experimentation and effort. As such, the claims are invalid for lack of enablement. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1372, 1379 (Fed. Cir. 2007) (affirming summary judgment of invalidity for lack of enablement where, among other things, inventors had not reduced claimed system to practice and "producing such a system would have required more experimentation and testing"). Dr. Wang explained the difficulty and amount of

effort Ariosa expended, after rejecting the Z-score approach, to develop and implement a complex algorithm to work in a targeted sequencing approach, and how there was no available literature to provide any guidance. Trial Tr. 1344:8-10; *id.*, 1345:16-1346:1. Dr. Cantor likewise confirmed that Sequenom, the NIPT company at which he served as Chief Scientific Officer, also tried to develop a nonrandom approach as claimed in the '430 patent, but was unable to do so. *Id.*, 1479:5-1481:12. As the Federal Circuit has observed, that the alleged infringer's "expert was not able to carry out the entire process as set forth in the . . . patent" supported a claim of nonenablement. *Old Town Canoe Corp. v. Confluence Holdings Corp.*, 448 F.3d 1309, 1320 (Fed. Cir. 2006).

Plaintiffs' reliance on the Z-score of the incorporated shotgun sequencing references fails for a further reason. The '430 patent does not claim using a Z-score to determine the presence or absence of a fetal aneuploidy. Instead, it purports to claim any and all ways of determining the presence or absence of a fetal aneuploidy in a nonrandom sequencing approach, as long as it involves using sequence reads from the chromosome tested for aneuploidy and sequence reads from a different chromosome. Under settled law, "[t]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the ***full scope*** of the claimed invention without 'undue experimentation.'" *MagSil Corp.*, 687 F.3d at 1380-81 (affirming summary judgment of non-enablement). *In re Wright*, 999 F.2d 1557, 1561, 1564 (Fed. Cir. 1993) (claims not enabled because the specification's "one example could" not be "extrapolated" to "make and use the full scope of the claimed invention without 'undue experimentation'"). Even accepting Plaintiffs' Z-score argument at face value, there is simply no dispute that the '430 patent fails to enable any and all ways for determining aneuploidy using a nonrandom sequencing approach. The full scope of the claims is thus indisputably not enabled. *See Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 691 (Fed. Cir. 2001) (affirming district court's invalidation of claims for lack of enablement; claimed method could not be performed "without significant mathematical manipulation" of information, yet specification did not disclose details of computer program that could perform such process).

At the very most, the '430 patent provides a mere starting point for a nonrandom approach to fetal aneuploidy analysis. But a patent that merely provides "a starting point" "to engage in an iterative, trial-and-error process to practice the claimed invention," lacks enablement. *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1386 (Fed. Cir. 2013). The evidence therefore demonstrates that the specification of the '430 patent does not enable the full scope of the claimed invention and thus the asserted claims are invalid for lack of enablement.

III. CONCLUSION

For the foregoing reasons, the Court should grant JMOL in favor of Ariosa on its license defense to the '794 patent with respect to Harmony V1 and on Ariosa's affirmative counterclaims against Illumina. The Court should also grant JMOL of invalidity of the asserted claims of the patents-in-suit, or in the alternative a new trial on invalidity.

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Respectfully submitted,

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